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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Number 11 continued.

Applicant's arguments filed 4/12/2010 regarding the rejection of claims over James et al. (US 6228401), and also over James et al. (US 6228401) in further view of Neri et al. (US 3995060) have been fully considered, but are not persuasive. Applicant argues that Finality of the Office action dated 1/12/2010 was premature and that it should be withdrawn since claim 41 is listed as being rejected over James et al. and it was not rejected over this reference in the non-final rejection. This argument is not persuasive. It is clear from reading the body of the rejection over James et al. that claim 41 was listed mistakenly in the heading of the rejection. The body of the rejection makes no reference to claim 41 which requires the flutamide to be recrystallized. Rather, claim 41 is explicitly addressed in a rejection under 35 USC 103 over James et al. in further view of Neri et al. Furthermore, comparing the body of the rejection from the Final rejection dated 1/12/2010 to the non-final rejection dated 8/11/2009, one quickly discovers that the two rejections are identical. It is also noted that applicant has not provided evidence of unexpected results to rebut the rejection of claim 41.

Applicant also requests that finality be withdrawn because the Examiner failed to follow the principles of compact prosecution because the Examiner failed to articulate on the record with specificity sufficient to support a prima facie case of obviousness (MPEP 2164.01) since in three places in the response to applicant's arguments, the Examiner refers to Jones et al. rather than James et al. This argument is not persuasive. First, it is highlighted that applicant acknowledges that this appears to be

an obvious typographical error (arguments p. 8, final paragraph). Furthermore, it is clear that the reference to Jones et al. is a clear typographical error as nowhere in the body of the actual rejection is Jones et al. referenced. Additionally, the context of the arguments surrounding Jones et al. is clearly subject matter that was discussed explicitly in the James et al. reference. In conclusion, because the body of the rejection refers exclusively to James et al., there is no ambiguity in the prima facie case of obviousness presented to applicant and from the context of the arguments, it is clear that reference to Jones et al. is a clear typographical error.

The remainder of applicant's arguments hinge around the product-by-process limitation in the instant claims. Applicant argues further that the Examiner has failed to present a prima facie case of obviousness because James et al. teach that flutamide compositions having particle sizes greater than 26.0 μm failed to provide blood levels consistent with that of Eulexin® (col. 4, lines 43-55). Applicant argues that the compositions of James et al. were prepared by a wet granulation method and does not suggest that the flutamide has been subjected to intensive mixing in a forced-action mixer with at least one surface-active substance. Regarding product-by-process type claims, applicant argues that the courts have held that the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product (In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). To this

effect applicant argues that “unmilled” imparts physical and structural characteristics of flutamide. Whereas applicant has appreciated that subjecting unmilled flutamide to intensive mixing in a forced-action mixer with at least one surface active substance imparts distinct structural characteristics to the final product including the release of 92-1--% of the active ingredient (p. 17 specification) and an X50 value of greater than 26 μm. Applicant concludes that because the pharmaceutical composition of James et al. has X50 values smaller than 26 mm, the instant composition is therefore distinct from the composition of James et al. Applicant also argues that the present invention cannot be viewed as a predictable result because it was not known prior to the present invention that surface-active substances had any influence on the particle size or bioavailability of flutamide. These arguments are not persuasive.

First, it is noted that applicant’s claims are not directed to a method of manufacture, but are rather directed to a product. As also addressed explicitly in the rejection over James et al., it is important to note that the phrases "unmilled" with respect to flutamide and "wherein the flutamide has been subjected to intensive mixing in a forced-action mixture [mixer] with the at least one surface-active substance" of claim 37 and "wherein the formulation is mixed in a forced-action mixer for 1 to 180 minutes” in claim 61, and "wherein the formulation is mixed in a forced-action mixture [mixer] for 3 to 60 minutes” of claim 62 are recitations of product-by-process limitations. Since claim 37 is a product-by-process claim, and all pending claims depend from claim 37, therefore, all pending claims are product-by-process claims. “[E]ven though product-by-process claims are limited by and defined by the process, determination of

patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim **is the same as or obvious** from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (emphasis added). For more information regarding product-by-process claims, please refer to MPEP 2113. Because James et al. teaches compositions having the exact same ingredients as required by the instant claims, the exact same means of mixing as recited in the instant product-by-process type claims, and further teaches that it is well known in the flutamide formulation art that varying the mixing speed, the amount of flutamide fed into the mixer and the mixing period all influence the resulting size and surface area of the resultant flutamide particles, the limitations of these product-by-process claims is met. It would be obvious to one of ordinary skill in the art to adjust the mixing time. One would be motivated to do so in order to affect the resultant particle size. As discussed above, this particle size has been made obvious over the teachings of James et al.

In summary, the claimed particle sizes of the flutamide composition claimed have been made obvious. Applicant has not provided evidence of unexpected results suggesting that the flutamide composition made by the claimed product-by-process steps is somehow different in an unobvious way or unexpected. Further it is noted that applicant is not claiming bioavailability or release amounts, nor is applicant claiming a method of manufacture. As such the claimed product is obvious over the teachings of James et al.

Regarding the argument of predictability, again it is noted that the instant claims are product-by-process claims. It is noted that the point that applicant's argument hinges on is that applicant discovered that surface active substances have an influence on the particle size and bioavailability of flutamide. First, this point has not been verified. As addressed above and in the rejection, there are several factors which contribute to flutamide bioavailability and particle size. Among these include mixing speed, the amount of flutamide fed into the mixer and the mixing period. Applicant has not provided any data suggesting that intensive mixing of flutamide with a surface-active substance is *the* factor responsible for the claimed particle sizes. As James et al. teach, there are several means by which to arrive at different particle sizes. Because of this fact and the fact that the compositions as taught by James et al. contain all the exact ingredients required by the instant product claims, applicant's product-by-process claims are held prima facie obvious over the teachings of James et al.

Applicant argues that the one of the motivation statements set forth by the Examiner, namely that it would have been obvious for one of ordinary skill in the art to arrive at an X50 value of greater than 26 μm with the motivation for milling/mixing less would reduce heat degradation of the product is a teaching away based on the James et al. reference. This argument is not persuasive and it was addressed in full in the previous Office action dated 1/12/2010.